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Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
Environmental Protections Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460-0001

Re: Phenol, 4,4'-(1-methylethylidene)bis-, CASRN 80-05-7

Dear Sir or Madam:

The following information is being submitted on behalf of the Polycarbonate/BPA Global Group of the American Chemistry Council. The Polycarbonate/BPA Global Group includes the following companies that manufacture the subject chemical in the US: Bayer MaterialScience LLC, The Dow Chemical Company, SABIC Innovative Plastics, and Sunoco, Inc (R&M).

This information is provided pursuant to current guidance issued by EPA indicating EPA's interpretation of Section 8(e) of the Toxic Substances Control Act. As these are preliminary observations, no determination has been made as to whether these observations actually present a significant risk of injury to health or the environment.

The subject chemical is currently under study in a developmental neurotoxicity study conducted according to internationally accepted guidelines (U.S. EPA OPPTS 870.6300 and OECD Guideline 426) and Good Laboratory Practices. The study was initiated in July 2008 and a final report is expected to be available in 2009. This letter is to inform you of preliminary clinical observations of offspring recorded in this study.

Study Outline

The study design called for twenty-four pregnant CD® (Sprague-Dawley) rats per group to be administered the subject chemical (via dietary feed) at levels of 0, 0.15, 1.5, 75, 750, or 2250 ppm from gestation day 0 until lactation day 21 (inclusive). These dietary levels correspond to approximately 0, 0.01, 0.1, 5, 50, or 150 mg/kg-day. Due to the large number of groups, the study consists of two cohorts (4 weeks apart) of 12 mated females per group. Maternal observations include appearance and behavior, detailed clinical observations, body weight, food consumption, parturition and lactation, litter size, organ weights, and microscopic examination. Offspring evaluations include body weight, appearance and behavior, developmental landmarks, surface righting reflex, detailed clinical observations, motor activity, auditory startle, learning and memory, brain weight, and neuropathology.

Clinical Observations

The testing laboratory recently provided preliminary, unaudited data summarizing clinical observations in offspring for postnatal days 4 and 11 (cohorts 1 and 2), and postnatal days 21 and 35 (cohort 1 only, cohort 2 animals have not yet reached the age for further evaluation on postnatal days 21 and 35). Observations described as convulsions were recorded for a small number of offspring in the two highest dose groups when observed in an open field as part of the Functional Observational Battery. These observations were recorded if the animal repeatedly jumped or repeatedly bounced in the air with all four limbs momentarily leaving the surface of the open field by approximately ¼ inch, or if the animal appeared to be repeatedly startled or appeared to "jump" but without all four limbs leaving the surface of the open field. In either case, the duration of the event was approximately 5 to 10 seconds.

Interpretation of these observations is currently limited as summarized below:

- The incidences of these observations were low: 2 of 44 animals from the 50 mg/kg-day group and 4 of 46 animals from the 150 mg/kg-day group.
- The observations were recorded only on postnatal day 11, but not on postnatal days 4, 21 or 35 (as noted above, the cohort 2 animals have not yet reached postnatal days 21 and 35).
- No similar observations have been noted in daily cage-side observations of all offspring.
- The observations are limited to the two highest dose groups (approximately 50 and 150 mg/kg-day). The highest dose was selected to induce toxicity as required by the applicable testing guidelines. In comparison, typical human exposure is many orders of magnitude lower than the dose levels of the observations.
- To date, no other treatment-related clinical observations were reported at any other dose level or at any other time point.
- Since these preliminary observations are at an early point in the study, it is not yet possible to corroborate the observations with any other toxicity, neurobehavioral or neuropathological parameters.

Overall, given the preliminary nature of these observations, it is not yet possible to assess whether these observations are treatment-related or of any biological or toxicological significance. Data collection for other neurobehavioral and neuropathological parameters is still in progress. The final report will be forwarded to the TSCA 8(e) coordinator promptly when it becomes available.

Please contact me if you have any questions.

Sincerely,

Steven G. Hentges, Ph.D.
Executive Director
Polycarbonate/BPA Global Group